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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,785	03/16/2007	Thomas Rothmann	00051-0031-001	1799
91436 7590 07/07/2010 Fanelli Strain & Haag PLLC 1455 Pennsylvania Ave., N.W., suite 400 Washington, DC 20004				
EXAMINER				
ETHERTON, BRADLEY				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,785

Applicant(s)

ROTHMANN ET AL.

Examiner

Bradley Etherton

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 18-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is a response to Applicant's amendment filed on April 13, 2010.

Claims 1-29 are pending in the application. Claims 1-9, and 18-23 have been cancelled, claims 10-17 and 24 have been amended, and new claims 25-29 are acknowledged.

The previous objections to the Specification are withdrawn in light of Applicant's amendment. The previous 35 USC §102(b) rejections of claims 1-7, 9-16, and 18 are withdrawn in light of Applicant's amendments. The previous 35 USC §103(a) rejections of claims 8, 17, and 19-24 are withdrawn in light of Applicant's amendments.

New grounds of rejection are necessitated by Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bloch**, et al. (U.S. 5,411,876), in view of **Rothmann**, et al. (U.S. 2003/0065152).

In regard to claim 10, **Bloch** discloses a method for improving the processing of polymerase chain reaction (PCR) solution (Abstract). **Bloch** teaches that PCR reactions are conducted in aqueous solutions (col. 1, lines 27-30) in automated systems (col. 2, lines 22-43). **Bloch** discloses that the automated systems extensively handle the liquid samples by introducing and withdrawing liquid from the PCR tubes (col. 10, line 65 to col. 11, line 4). Therefore the automated systems are considered to be open systems (col. 3, lines 32-54).

Bloch discloses that mineral oil, as well as waxes and greases, may be added to the surface of the aqueous solution as a barrier to both evaporation and contamination (Abstract and col. 8, lines 37-41). Mineral oil is comprised of a mixture of water immiscible hydrocarbons (col. 11, lines 5-12).

During the course of processing the samples, pipets which deliver liquids or withdraw liquids penetrate the barrier on the aqueous solution in order to introduce or withdraw beneath the barrier (col. 9, lines 7-31). Therefore, **Bloch** is considered to disclose processing the aqueous solution under the contamination barrier.

Bloch does not appear to explicitly disclose that (1) covering the aqueous phase with mineral oil prevents contamination during transfer of said aqueous solutions, and/or prevents formation of aqueous aerosols, while allowing for removal and processing of the aqueous solutions under the contamination barrier or (2) that the mineral oil is comprised of branched or unbranched hydrocarbons having 6 to 16 carbon atoms.

However, **Rothmann** discloses a method which prevents contamination during the separation and purification of biopolymers such as nucleic acid-containing polymers (Abstract and paragraph [0002]). **Rothmann** discloses adding a layer of an immiscible hydrocarbon on top of an aqueous solution of the biopolymer (paragraph [0011]). The layer prevents cross-contamination of samples due to aerosol formation when the samples are processed (paragraph [0009]). Mineral oil is particularly preferred for this use (paragraph [0013]). **Rothmann** also teaches that hydrocarbons having 8 to 12 carbon atoms are suitable for this use. Since the range of 8 to 12 carbon atoms overlaps the range of 6 to 16 carbon atoms, the range recited in claim 1 is considered *prima facie* obvious.

Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the mineral oil barrier as taught by **Bloch** and replace the mineral oil with C₆ to C₁₆ hydrocarbons as taught by **Rothmann** in order to

prevent aerosol formation and because mineral oil is a mixture of distillates from different sources (**Rothmann**, paragraph [0014]) while C₆ to C₁₆ hydrocarbons having specific compositions are pure, well-defined chemical species.

In regard to claims 11-17, **Rothmann** discloses that the hydrocarbon may be (i) an unsubstituted hydrocarbon, (ii) a substituted hydrocarbon, (iii) a cyclic hydrocarbon, (iv) a branched or unbranched acyclic hydrocarbon, (v) a branched or unbranched alkane, or (vi) octane, nonane, decane and mixtures thereof (paragraphs [0012]-[0013]). **Rothmann** also discloses hydrocarbons containing 8 to 12 carbon atoms, as discussed above.

Rothmann does not disclose whether the cyclic hydrocarbons are saturated or unsaturated. However, alkanes are preferred hydrocarbons, so **Rothmann** is considered to disclose that the cyclic hydrocarbons are saturated cyclic hydrocarbons.

In regard to claim 24, **Rothmann** discloses octane, nonane, and decane, which are unbranched alkanes having 8 to 10 carbon atoms. Since the range of 8 to 10 carbon atoms overlaps the range of 8 to 12 carbon atoms, the range recited in claim 24 is considered *prima facie* obvious.

Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Bloch**, in view of **Kosak**, et al. (U.S. 5,968,729).

In regard to claim 25, **Bloch** discloses all of the limitations of claim 25, as discussed above in regard to claim 10, except **Bloch** does not appear to explicitly disclose that the contamination barrier comprises silicone oil.

However, **Kosak** discloses a method to seal an aqueous PCR tube with a grease or wax layer (Abstract). **Kosak** discloses that the layer provides a barrier against contact with the atmosphere (col. 5, lines 63 to col. 6, lines 15). This is considered to be the barrier against evaporation and contamination disclosed by **Bloch**, as discussed above. **Kosak** discloses that acceptable greases must be inert and immiscible with water. A preferred grease for covering the aqueous solution is silicone grease (col. 10, lines 7-11).

Kosak does not disclose silicone oils for use as barriers on aqueous PCR solutions. However, **Bloch** teaches that oils, greases, and waxes are all suitable for use as barriers on aqueous PCR solutions, as discussed above. Therefore, it is considered *prima facie* obvious that silicone greases and silicone oils are both suitable for use as such barriers.

Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the mineral oil barrier of **Bloch** and utilize a silicone barrier material as taught by **Kosak** because it is easier to penetrate an oil layer than a grease layer, which reduces the likelihood of aerosol generation (**Bloch**, col. 9, lines 24-31).

Claim 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bloch**, in view of **Kosak**, as applied to claim 25 above, and further in view of **Moretto**, et al. ("Silicones" in Ullmann's Encyclopedia of Chemical Technology, Wiley-VCH, 2002, on-line posting June 15, 2000).

In regard to claim 26, **Bloch**, in view of **Kosak**, discloses the process of claim 25, as discussed above, but does not appear to explicitly disclose silicone oils that are comprised of unbranched chains of silicon and oxygen atoms having 10 to 1000 silicon atoms.

However, **Moretto** discloses that the most important silicone fluids are methyl silicone fluids comprised of unbranched chains containing silicon and oxygen atoms (Sec. 3.1 and p.8, Table 4). These silicone oils contain from about 4 silicon atoms to about 4000 silicon atoms (p. 10, Sec. 3). **Moretto** further discloses that silicone oils having about 20 to 300 silicon atoms have the same viscosity as mineral oils (p. 11, Figure 6). Silicone fluids having the same viscosity as mineral oils are considered silicone oils. Since the range of 22 to 300 silicon atoms overlaps the range 10 to 1000 silicon atoms, the range recited in claim 26 is considered *prima facie* obvious.

Therefore, at the time of the invention, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the silicone oil barrier as taught by **Bloch**, in view of **Kosak**, with unbranched silicones containing 10 to 1000 silicon atoms because those silicones are the most important silicone fluids and are readily available (**Moretto**, Sec. 3.1).

In regard to claims 27-28, **Moretto** discloses silicone fluids that contain about 22 to 300 silicon atoms, as discussed above. Since the range of 22 to 300 silicon atoms overlaps the ranges of (i) 30 to 500 silicon atoms, and (ii) 50 to 150 silicon atoms, the ranges recited in claims 27-28 are considered *prima facie* obvious.

In regard to claim 29, **Moretto** does not explicitly state that silicone fluids are silicone oils. However, one would expect that silicone fluids having the same viscosity as mineral oils would be considered silicone oils, as discussed above.

Response to Arguments

Applicant's arguments have been fully considered, but are considered moot in light of the new grounds of rejection. The Examiner respectfully disagrees with Applicant's arguments that **Bloch** relies solely on waxes and greases as overlays on the aqueous solution in a PCR product. **Bloch** discloses that mineral oils are well known and commonly used as barriers in this application (Abstract). Otherwise, the Examiner agrees with Applicant's arguments regarding the differences in the performance of waxes and oils as barriers to PCR contamination.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley Etherton whose telephone number is (571) 270-5478. The examiner can normally be reached on Monday through Friday, 7:30 a.m. to 5:00 p.m. EST, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Caldarola can be reached on (571) 272-1444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley Etherton/
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